



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	0075530-000008	7903
21839 7590 06/18/2009 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER DICKINSON, PAUL W	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 06/18/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,544	<b>Applicant(s)</b> COSTANZO ET AL.	
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 2/18/2009 and 3/13/2009 have been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Response to Arguments***

***Claim Rejections - 35 USC § 103***

The rejection of claims 21-41 under 35 U.S.C. 103(a) as being unpatentable over US 6391337 ('337) in view of US 6079968 ('968) in further view of US 4684534 is maintained. The rejection of claims 31 and 42-47 under 35 U.S.C. 103(a) as being unpatentable over '337 in view of '968 is maintained.

Applicant argues (1) '337 does not disclose an active substance in the form of microcrystals or microgranules that are uniformly coated with a polymer coating. Applicant argues (2) '337 does not disclose a tablet disintegrating in the mouth on

contact with saliva in less than 30 seconds. Applicant argues (3) that it would not have been obvious to combine the above references to arrive at the presently claimed invention.

Applicant's arguments have been fully considered but are not found persuasive.

(1) The Examiner must give the claims their broadest reasonable interpretation.

The Examiner is interpreting "microcrystals or microgranules that are uniformly coated with a polymer coating" to mean that the active substance may be in the form of (uncoated) microcrystals, or in the alternative, in the form of microgranules that are uniformly coated with a polymer coating. '337 discloses the desirability of using crystalline active substances in direct compressible tablets (see col 2, lines 56-63), and further teaches using microscale acetaminophen in the invention (see abstract; col 6, lines 17-19). Accordingly, it would have been obvious to use (uncoated) microcrystals of acetaminophen in the direct compressed dosage forms of the invention.

(2) A composition cannot be separated from its properties, and as the dosage form rendered obvious by '337 in view of the secondary references meets all the structural limitations of the presently claimed invention, it must also have all the properties of the presently claimed invention. Applicant argues the necessity of coating the active substance with a polymer coating, but as stated above, the present claims do not require the active substance, when in the form of microcrystals, to be coated.

(3) Applicant's argument that one skilled in the art wanting to decrease the friability of '337 would have no reason to use the device of '968 is not found persuasive. '337 clearly teaches the incorporation of lubricants (see col 1, lines 16-25). It would

have been obvious to spray at least some amount of lubricant to the tablet die, as this is a known means in the art of preventing the compressed tablet from sticking to the die, while at the same time minimizing caking of lubricants onto the tablet die. As the surface lubricant remains only on the surface, and not mixed with the bulk contents of the tablet, this ingredient should have a minimum impact on the tablet's friability.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 21, 31, and 45 recite "microgranules that are uniformly coated with a polymer coating". Although the specification and original claims disclose coating microgranules with polymer coatings (see specification, page 1, line 29 to page 2, line 2), there is no support for a "uniformly coated" microgranule. The recitation of "a coating" is open to any degree of coating, whether partial (covering a fraction of the surface) or full (covering the entire surface), the latter being synonymous with "uniformly

coated". As the specification and original claims do not disclose the more specific embodiment of coating presently claimed ("uniformly coated"), the skilled practitioner would not believe that Applicant had possession of the invention at the time of filing.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

May 23, 2009